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10/510,492	05/23/2005	Andreas Menne	T4494-16088US01	1537

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MILES & STOCKBRIDGE PC
1751 PINNACLE DRIVE
SUITE 500
MCLEAN, VA 22102-3833

EXAMINER	
ABRAHAM, SALIEU M	
ART UNIT	**PAPER NUMBER**
3768	

NOTIFICATION DATE	DELIVERY MODE
03/18/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocketing@milesstockbridge.com
sstiles@milesstockbridge.com

Office Action Summary	Application No.	Applicant(s)	
	10/510,492	MENNE ET AL.	
	Examiner	Art Unit	
	SALIEU M. ABRAHAM	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,9 and 12-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 8-9 and 12-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-6, 8-9 and 12-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,413,230 to Haupt (Haupt) in view of US Pat. No. 4,972,826 to Koehler (Koehler).

Note: Examiner has interpreted ***transmission element*** to broadly include any element (focusing or non-focusing) that allows a generated (extracorporeal pressure) wave to be transmitted or passed across it from an entry boundary to an exit boundary as is well accepted in the art (see US2003/0199857 figs. 1-2, 5A and 5B, and 7A and 7B, and 0056-0057) and disclosed by applicant (see section 0003 in instant application).

In Reference to Claims 1, 13 and 17

Haupt teaches:

A medical instrument for the treatment of biological tissue, comprising:

a) a means for generating extracorporeal pressure waves, (see abstract, and figure 1)

and

b) a transmission element (2) for coupling the pressure waves into the body of living beings,

c) pressure wave coupling to the "transmission element by an impact member (10) hitting a transmission element (2) and the pressure wave propagates in and travels through the transmission element (2)",

d) a “typical” value for the stroke of the (exit boundary of the) transmission element of less than 0.5 mm (col. 4, lines 55-57)

e) an inwardly curved exit boundary surface for pressure wave coupling into the biological tissue (see col. 2, lines 59-65) and a monolithic (e.g. single-piece) horn-shaped transmission element having larger diameter at the exit boundary surface than at an axially opposite entry boundary surface (see cols. 2, lines 59-67 and 3, lines 1-4).

However, Haupt fails to teach where the transmission element focusedly couples the pressure wave into the biological tissue.

In a related application using extracorporeal shock waves for biological tissue treatment, Koehler teaches the use of various focused (fig. 4, element 18) and non-focused (fig. 4, element 19) transmission elements for customizing shock wave generated pressure pulse profiles for medical purposes targeted toward providing therapy to a specific anatomical site in lieu of areas surrounding the target site (see figs. 1-4 and cols. 1, lines 7-12, 2, lines 1-12 and lines 23-29). Koehler further teaches the use of a horn-shaped transmission element with larger diameter than the entry element’s boundary (fig. 4, element 19) to facilitate wave propagation and focusing on the target site (see fig. 4, element 18 and col. 3, lines 37-46). Koehler cites the

combination of the various transmission elements (fig. 4, 18,19; 21-26 in fig. 5) as a key benefit in shaping the pressure pulse for therapeutic effect (cols. 3, lines 37-68 and 4, lines 1-5). He further suggests that the elements may be juxtaposed to one another (e.g. made integral; see col. 3, lines 58-61) in order to customize the pressure pulse (as cited earlier ;see note section supra).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have the incorporated the focused transmission apparatus of Koehler in the medical instrument of Haupt in order to better direct and focus the generated pressure (pulse) wave on the intended anatomical target as taught by Koehler.

In Reference to Claim 2

Haupt in view of Koehler has been shown to teach all of the limitations of claim 1. Haupt in view of Koehler further discloses:

The medical instrument as defined in claim 1, wherein the means for generating the pressure waves is an impact member (Haupt fig. 1, 10) guided in a housing and adapted to reciprocated by means of a drive means, the impact member (10) exerting one or more impulses on the transmission element (2) and inducing a pressure wave in the transmission element (2) due to the impulse, said pressure wave propagating to the exit boundary surface (24) of the transmission element (2). **(**see Haupt col. 4, lines 1-57**).**

In Reference to Claim 3

Haupt in view of Koehler has been shown to teach all of the limitations of claim 2. Haupt in view of Koehler further discloses: (see Haupt fig. 1 for referenced structural elements below)

The medical instrument as defined in claim 2, characterized wherein the impact member

(10) is arranged coaxially to the transmission element (2).

In Reference to Claim 4

Haupt in view of Koehler has been shown to teach all of the limitations of claim 1. Haupt further discloses:

The medical instrument defined in claim 1, wherein the pressure wave source may be driven periodically, the impact member (10) and the transmission element (2) being self-returnable. (see col. 2, lines 26-46).

In Reference to Claim 5

Haupt in view of Koehler has been shown to teach all of the limitations of claim 1. Haupt in view of Koehler further discloses:

The medical instrument as defined in claim 1, wherein the impact frequency of the impact member (10) is about 1 to 30 Hz, preferably 1 to 12 Hz. (see Haupt col. 4, lines 53-57).

In Reference to Claim 6

Haupt in view of Koehler has been shown to teach all of the limitations of claim 1. Haupt in view of Koehler further discloses:

The medical instrument as defined in claim 1, wherein a spring/damping element (Haupt fig. 1, 30) is provided between the transmission element (2) and the housing (4).

In Reference to Claim 8

Haupt in view of Koehler has been shown to teach all of the limitations of claim 1. Haupt in view of Koehler further discloses: (see Haupt fig. 1)

The medical instrument as defined in claim 1, wherein an intermediate element is arranged between the impact member (10) and the transmission element (2), which intermediate element passes an impulse from the impact member (10) to the transmission element (2) (see col. 2, lines 46-52).

In Reference to Claim 9

Haupt in view of Koehler has been shown to teach all of the limitations of claim 1. Haupt in view of Koehler further discloses:

The medical instrument as defined in claim 1, wherein the outer edges of the exit boundary surface of the transmission element are rounded or provided with a protective coating (see col. 2, lines 64-65).

In Reference to Claim 12

Haupt in view of Koehler has been shown to teach all of the limitations of claim 1. Haupt in view of Koehler further discloses:

The medical instrument as defined in claim 1, wherein the impedance-adjusting media are provided between the exit boundary surface (24) of the transmission element (2) and the biological tissue for improving the coupling of the pressure wave into the biological tissue. (see claim 25 and col. 3, lines 5-10).

In Reference to Claims 14-16

Haupt in view of Koehler has been shown to teach substantially the entire cited claim

features (see claim 13 and other rejections supra). In addition, Haupt further teaches wherein the impact member hits an entry boundary face of a transmission element and the impedance –adjusting means is an acoustically conductive medium located next to/around the opening exit boundary surface (see Haupt col. 3, lines 5-10 and 58-67).

In Reference to Claims 18-23

Haupt in view of Koehler has been shown to teach substantially all of the cited claim features (see claim 17 and other rejections supra). These include a medical instrument as defined in claim 17, wherein: (see Haupt fig. 1 for cited diagram reference marks)

the means for generating the pressure waves is an impact member (10) guided in a housing and adapted to be reciprocated by means of a drive means such that a pressure wave is generated and routed through a transmission element (see Haupt cols. 2, lines 67-68, 3, lines 1-5 and 4, lines 1-34),

the impact frequency of the impact member (10) is in the range of 1 to 30 Hz, preferably 1 to 12 Hz (see Haupt col. 4, lines 53-57),

a spring/damping element is provided between the transmission element and the housing (see Haupt fig. 1, element 30),

the exit boundary surface (24) of the transmission element (2) travels a stroke of less than 0.5 mm due to the impact member (10) hitting the transmission element (2) (see Haupt cols. 2, lines 41-45 and col. 4, lines 55-57),

an intermediate element (9) is arranged between the impact member (10) and the transmission element (2), which intermediate element passes an impulse from the impact member (10) to the transmission element (2) (see col. 2, lines 46-52), and

impedance- adjusting means are provided between the exit boundary surface (24) of the transmission element (2) and the biological tissue for improving the coupling of the pressure wave into the biological tissue, and wherein the impedance-adjusting means is an acoustically conductive medium located substantially within the entirety of said concavely outwardly opening exit

boundary surface (24) (see Haupt col. 3, lines 5-24).

Response to Arguments/Remarks

3. Applicant's arguments with regard to claims 1-6, 8-9 and 12-23 filed December 12, 2009 have been fully considered, but they are not persuasive.

4. With respect to applicant's arguments regarding transmission element exit boundary shape (i.e. concavity), the primary reference to Haupt teaches substantially all claim structural limitations and is relied upon primarily to teach coupling of pressure waves in to biological tissue (see section 6a-c, from June 24,2009 office action <POA>). Examiner concurs that Haupt does not explicitly teach an inwardly curved exit boundary surface, though the reference fairly suggests modifying pressure wave generation and proliferation components of the exit boundary surface (e.g. probe tip) in to other shapes (e.g. concave; see Haupt, col. 2, lines 59-65) as necessary for treatment. However, the secondary reference to Koehler was discloses the exit boundary shape and exponential horn limitations (see POA, p. 4, last para. and p. 5, first para.). Examiner respectfully disagrees with applicant's assertion that Koehler fails to disclose a transmission element in the shape of an exponential horn (18) and that the combination of elements (plate and lens) of Koehler when incorporated in the invention of Haupt would not yield applicant's proposed invention. Examiner would like to redirect applicant to the POA note on page 3, section 6 in which Examiner states his interpretation of a "*transmission element*" based upon applicant's disclosure (0003) and the prior art (US2003/0199857 figs. 1-2, 5A and 5B, and 7A and 7B, and 0056-0057). In

this regard, Haupt in view Koehler substantially teaches applicant's the invention ***as claimed*** by applicant: a medical device with entry (Koehler, fig. 4, 19) and exit boundary components (18) that can be used to shape acoustically generated waves for transmission into tissue. Whether the components are separated or integrated monolithically is not required by the claims and Examiner has shown from the prior art that it is well known in the art to integrate separate transmission elements into a single, monolithic component (i.e. made integral; see US2003/0199857 figs. 1-2, 5A and 5B and 0056-0057). Furthermore, it has been held that forming in one piece an article which has formerly formed in two (or more) pieces and put together (e.g. made integral) involves only routine skill in the art (Howard v. Detroit Stove Works, 150 U.S. 164 <1893>). Lastly, the claims do not require that the transmission element(s) ***directly*** couple the pressure waves into biological tissue, but that "the transmission element has an inwardly curved surface ***configured such that the pressure waves may be coupled*** into the biological tissue and may be focused in the biological tissue." The components as described in Koehler fully meet this limitation as claimed (see fig. 4, elements 18, 5-7 and 11).

5. As a result of the items supra, the instant Office Action is now made **final**.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Salieu M. Abraham whose telephone number is (571) 270-1990. The examiner can normally be reached on Monday through Thursday 10:30 am - 7:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

3/12/10 SA

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768